EXHIBIT 4

ADA TROMBLEY v. 3M
CASE-SPECIFIC REPORT AND SITE REVIEW OF OPERATING ROOM
BAY PARK COMMUNITY HOSPITAL, OREGON, OHIO
January 3, 2019

I attended a site visit to Bay Park Community Hospital in Oregon, Ohio to review an operating room (Operating Room #3). I am aware that Ms. Trombley alleges that in December 2011, the use of a Bair Hugger during her right knee replacement surgery in this operating room caused her to develop a deep joint infection. In arriving at my case-specific opinions and observations on that operating room, I rely on my education, training and experience, as well as the general principles and opinions outlined in my previous reports and my trial testimony in *Gareis v. 3M*.

1) PRE-VISIT REVIEW OF INFORMATION

Prior to the visit, I was provided with a collection of documents in a pdf package (see Reference Listing below). This package included the following documents produced by Bay Park Hospital:

a) Excerpt from a mechanical drawing depicting the operating room
b) A list of policies and procedures
c) A brochure of a Sterilaire MVCA-1010 Modular Vertical Clean Air System

The plan view of the operating room shows supply ductwork distribution to the center of the room, feeding a central diffuser array. There are four exhausts shown on the drawing around the room on the perimeter walls. As discussed below, the drawing did not match what I observed during the site visit. I am informed that counsel for Bay Park Hospital was unable to provide any other drawings of the room.

The Sterilaire System brochure describes a supply system that claims the following:

a) "laminar"[1]air delivery
b) Room-side HEPA filters in the ceiling supply
c) A total air supply volume of 7200 cfm (108 room air changes based on an assumed 4000cf room volume)
d) Operation at 2 speeds, either 40 or 75 fpm
e) Conforms to Federal Standard 209E for Class 100 clean room equipment
f) 4 direct drive blowers

[1] As discussed in my MDL report and previous deposition testimony, airflow in an operating room is not truly "laminar," in the sense of an uninterrupted flow from ceiling to floor. Equipment and personnel interrupt airflow from the ceiling, causing turbulence and eddy formation.

2) SITE VISIT

I attended a site visit Bay Park Community Hospital on January 3, 2019, accompanied by counsel for 3M (Corey Gordon and Peter Goss), counsel for the plaintiff (Ben Gordon), counsel for the Hospital (Kayla Henderson), and two Hospital Representatives (Glenn, Neil). The visit included the surgical floor and specifically the Operating Room where the surgery was performed. The following observations were made from this visit:

a) Layout

The layout of the room provided did not match what I observed at the visit. I measured the room to be 21'11" x 22'10" by 9'10" high. Figure 1 depicts a sketch of the operating room based on what I observed on January 3, 2019. All dimensions are approximate. There was an entry door from the surgical corridor, adjacent to the scrub sinks. There was another door on the opposite wall, that led to the sterile corridor. There were stainless steel cabinets in the room and work counters on the perimeter.

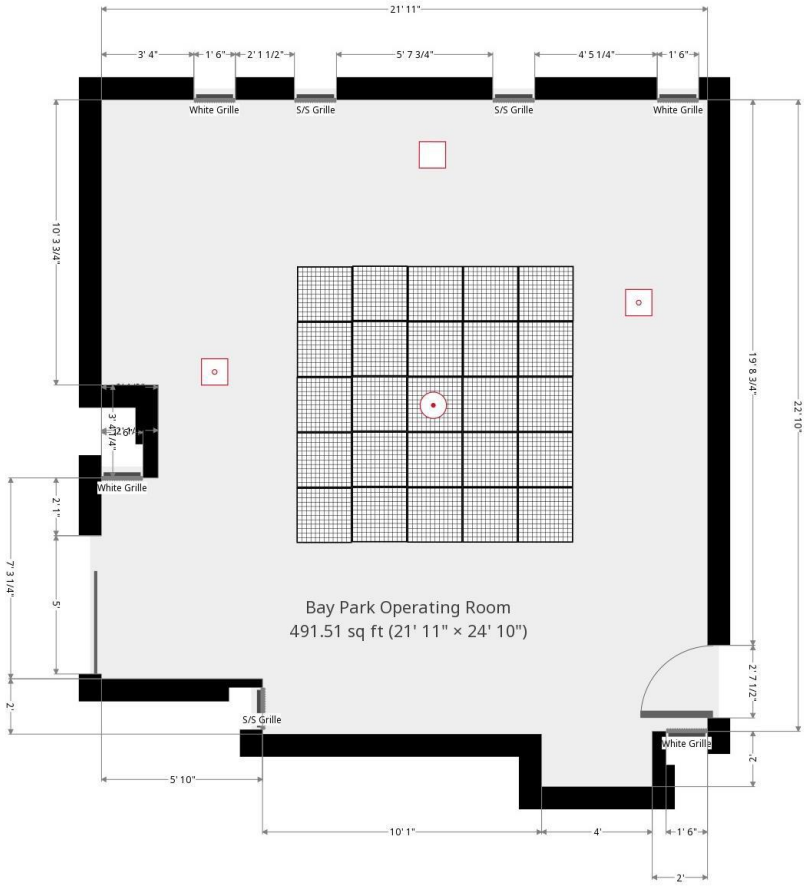

FIG. 1 BAY PARK OR #3 OBSERVED PLAN LAYOUT

b) Equipment

The operating room table was located approximately in the centre of the room. There was a stainless gas column that hung from the ceiling and two articulating arms that carried monitors and additional equipment. There were a number of pieces of equipment in the operating room, located primarily at the top end of the room near the head of the surgical table. The equipment included an electrocautery generator, anesthesia machine, a Bair Hugger warming unit, suction devices, numerous monitors, and other equipment that would typically be used during an orthopedic joint replacement procedure. I understand that Bay Park Hospital was unable to verify the exact equipment used during Ms. Trombley's 2011 procedure, but I would expect the same or similar equipment to have been used in that surgery. That equipment would have generated heat and air movement during the procedure.

c) Lighting

Two operating room lights hung from the centre of the ceiling. They were Stryker model, Visium LED 2. Counsel for the Hospital later stated that the surgical lights were likely not the same as the ones present during the surgery in 2011. I would expect very similar dish-type overhead lights to have been used during that surgery, which as I noted in my MDL report will create eddies and recirculation zones when air from the ceiling array passes over them.

d) Temperature, humidity and air controls

There was a Johnson Controls digital display on the wall that at the time of the visit, read 68.0F and 32.3% relative humidity. There was also a reading of 61.3F for "CVB Disch Temp", which I assume referred to a Constant Volume Box Discharge Temperature for the supply air to the room.

FIG. 2 JOHNSON CONTROLS DISPLAY

There was a switch on the on the wall, labelled “Laminar Sub-Cooling Enable/Disable Control”. There were two positions on the switch, “disable” and “enable”. The switch was in the “disable” position during the time of the site visit. Unfortunately, Bay Park Hospital did not provide any information about this system and its impact on airflow in the room. There was another panel on the wall, labelled “Power CP4-39,41 Control CP7-42”. An additional label had been added that read “For optimal air exchange, leave fan on all day”. The panel had start and stop buttons, a fault indicator light and a fan speed switch that had “high” and “low” positions. At the time of the visit, the switch was in the “low” position. This panel appeared to control the two-speed settings of the Sterilaire MVCA-1010 Modular Vertical Clean Air System. A Bay Park representative confirmed that during orthopedic procedures the switch is turned to “high.” According to the Sterilaire specifications, that setting corresponds to an air discharge velocity of 75 feet per minute.

FIG. 3 STERILAIRE SYSTEM CONTROLS

e) Air supply and return

As indicated on the Bay Park-provided drawing, there was a central primary supply diffuser array, that measured approximately 10' x 10' over the operating room table. Only the support for surgical lights penetrated the centre of the diffuser array.

The wall grille distribution was different than was indicated on the drawing that had been provided. Of the four return air grilles shown on the drawing, only three were present. Each one was a stainless steel grille, 18"x30" in size and approximately 4" from the floor. I was unable to confirm visually that these returns are fan-powered but it is my expectation based on the design of the room and the Sterilaire system that they were.

There were also an additional four white painted grilles, approximately 18"x18" in size and also 4" from the floor. There was a filter located behind these grilles and it was confirmed on site that air was being supplied into the room at these four locations. The supply grille located nearest the entrance to the sterile core is depicted in fig. 4 below.

FIG. 4 SIDE WALL SUPPLY GRILLE

Based on the observed dimensions, the room volume is approximately 4833 cubic feet. At the supply volume stated by the Sterilaire brochure of 7200 cfm, this would translate to 89 air changes per hour. Additional air supplied through the white grilles would increase this level even higher. ASHRAE 170 standard requires a minimum total supply of 20 air changes per hour.[a] This system greatly exceeds the ASHRAE 170 requirement and raises potential concerns for excessive turbulence.

Another concern is raised by the use of the Sterilaire system at the 75 fpm high setting. ASHRAE 170 requires an average supply velocity at the diffusers of 25-35fpm.[a] As I have discussed previously, this range is based on Memarzadeh's work and the interest in preserving the patient's protective thermal plume. Velocities above this level have a higher risk of eroding squames from surgical staff, overcoming the buoyant plume of the open wound and impinging particles into the surgical site, increasing the number of airborne bacteria and the risk of surgical site infections.[b] It appears, based on the Sterilaire brochure's claim that it conforms to clean room standards, that the Sterilaire system was designed according to clean room manufacturing concepts that are not applicable to or appropriate for operating rooms.

The four white grilles that are supplying air near the floor are also a concern for the room air distribution. The air blowing from these grilles so close to the floor will have a tendency to disturb particles on the floor and lift them into the air, creating a greater risk of increased

particles reaching the surgical site. This is especially true of the wall diffusers nearest the head of the surgical table. The placement of wall supply vents near the returns also creates irregular air patterns that are likely to increase turbulence in the room.

f) Floors and walls
The floors were made of a sheet product, with welded seams. FGI Guidelines require that "Floor finishes in operating rooms ….shall be ….monolithic"[c] "Monolithic" is defined as formed or composed of material without joints or seams.

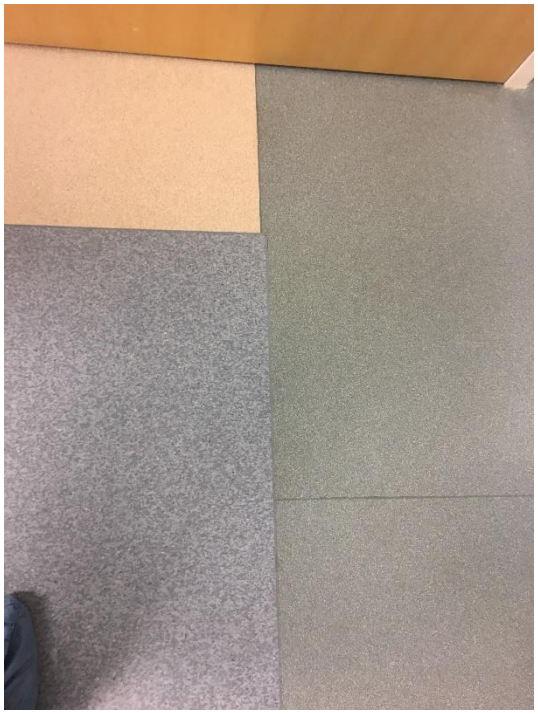

FIG. 5 OR FLOOR SEAMS

3) ADDITIONAL POST-VISIT INFORMATION

After the site visit, additional materials and information were provided. This included:

a) Notes from the original drawing provided, H2.1A, First Floor HVAC Plan Area –A. Note 11 confirmed that supply air ductwork was to be connected to the laminar airflow unit. Note 3 described connection of the 18x30 return grilles to the return ductwork, balanced to a return air volume of 450 cfm per grille.

b) A note from Hospital counsel that confirmed the filters behind the side wall supply grilles were MERV 8. Notably, this level of filtration is less than the Bair Hugger unit's rated efficiency of MERV 14.
c) A note from Hospital counsel that confirmed all grilles in the room were part of the original construction. On that basis I conclude that the HVAC system configuration I observed during the site visit was unchanged from the time of Ms. Trombley's December 2011 surgery.
d) An operating manual for the Sterilaire MVCA 1010RR Vertical Clean Air System.

4) SUMMARY OF OPINIONS

In addition to the general opinions expressed in my previous reports and my trial testimony in the *Gareis* matter, I intend to testify regarding my observations specific to the operating where Ms. Trombley's surgery took place. My opinions include:

a) The Bay Park OR departs from ASHRAE and FGI standards in several respects. Of particular concern are the high velocity of the ceiling diffusers, the use of wall-mounted supply vents near the OR floor, and the excessive air changes per hour. These features pose a risk of airborne contamination and impingement of contaminants on sterile instruments and the surgical wound.

b) The Sterilaire system does not deliver true "laminar" airflow. Airflow from the ceiling diffusers is interrupted by surgical lights, personnel, and equipment as it passes to the floor. These obstructions create turbulence. Moreover the side wall supply vents further disrupt airflow in the room. The Sterilaire system appears to have been constructed based on clean room manufacturing concepts. Clean room manufacturing utilizes higher velocities to clear contaminants, but in operating rooms these high-speed flows will overwhelm the patient's protective surgical plume. This greatly increases the risk of impinging particles on the patient surgical site.

c) The Bay Park OR contains numerous pieces of equipment that generate heat and air movement besides the Bair Hugger. These include the electrocautery machine, the anesthesia machine, the suction device, and the various computer terminals and monitors arranged about the room. All of these, in addition to staff movement and traffic in and out of the room, will affect airflow patterns in the room. While the exact equipment I observed during the site visit may not have been present during Ms. Trombley's procedure, I would expect the same or similar equipment to have been used.

d) I am familiar with the CAD model depicted in Plaintiffs' CFD simulations of the Bair Hugger. That model does not account for many features I observed in the Bay Park OR, including but not limited to the Sterilaire system; the number, placement, and power of the return vents; the presence of side-wall supply vents; heat generating equipment such as the electrocautery generator, anesthesia machine, and monitors; the number and location of doors; the placement

of the surgical boom lights; the size, shape and volume of the room, and the number of air changes per hour, among many other of the room's features. Given these differences, and the fact that Plaintiffs' simulations do not account for the movement of staff and the opening and closing of the OR doors, it is my opinion that those simulations cannot provide a reliable prediction of the movement of airborne particles during Ms. Trombley's surgery in December 2011.

5) REBUTTAL TO DR. JARVIS

Plaintiff expert William R. Jarvis, M.D. offers the following opinions in his case-specific Expert Report concerning the HVAC system in Bay Park OR #3:

- "the Bair Hugger has two mechanisms for contaminating the operative field with bacteria— through blowing non-filtered, non-sterile air"
- "I saw no evidence that the HVAC system in question may have been deficient in any respect or contributed in any way to this infection."
- "I reviewed the HVAC system operating manual, and it shows unequivocally that the air exchange rates were well in excess of what ASHRAE standards prescribe (20 exchanges/hour)."
- "Without some kind of affirmative evidence to suggest the system did not perform as designed, there is no plausible basis to suggest the HVAC system contributed to Mrs. Trombley's infection."
- "the Bair Hugger causes significant turbulence in the OR"

I am not aware that Dr. Jarvis has any credentials or training to offer expert opinions on HVAC issues. His statements about the HVAC system in OR #3 show a misunderstanding of how OR airflow works. Dr. Jarvis does not seem to be aware that the Bair Hugger contains a MERV 14 filter. While it is true that air exchange rates in OR #3 are "well in excess of what ASHRAE standard require," Dr. Jarvis does not appear to understand that the excessive velocity of the system will increase turbulence in the OR and potentially impinge shed particles on the surgical wound. In this respect, the system, as designed, raises concerns for wound contamination and infection risk. Furthermore, the air supply rate and velocity in this operating room greatly exceed the referenced CFD studies and as such would considerably further overpower any relative impact from the Bair Hugger.

6) REFERENCE LISTING

Bay_Park_0000001 – Bay_Park_0000044

Correspondence from Bay Park Community's Hospital's counsel, RCO Law, enclosing production Bay_Park_0000040 – Bay_Park_0000044

Photographs Bates Numbered 3MBHPF00100512 – 3MBHPF00100782

Photographs Bates Numbered 3MBHPF00100788 – 3MBHPF00100861

Expert Report of William Jarvis, M.D. concerning Ada L. Trombley

a. ASHRAE Standard 170, Ventilation of Health Care Facilities, 2017.
b. Weiser, M.C., MD, MEng, and Moucha, C.S., MD; Operating-Room Airflow Technology and Infection Prevention, Journal of Bone and Joint Surgery, Inc, 2018; 100; 795-804.
c. Guidelines for Design and Construction of Health Care Facilities, Facility Guidelines Institute, 2001, section 7.7.C7.c.

I reserve the right to amend or supplement this report based on the receipt of additional information.

I declare under penalty of perjury that the foregoing is true and correct.

February 14, 2019

Michael Keen